510K SUMMARY

APR - 8 2011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K101742

Company/Contact person

Lisa Charter
Manager, Regulatory Affairs
Thermo Fisher Scientific, Clinical Diagnostic Division
46360 Fremont Blvd
Fremont, CA 94538
Phone: (510) 979-5142
Facsimile: (510) 979-5422
Email: Lisa.Charter@ThermoFisher.com

Date Prepared

January 6, 2011

Regulatory Declarations

Common / Usual Name	CEDIA® Cocaine OFT Assay
Trade/ Proprietary Name	Thermo Scientific CEDIA® Cocaine OFT Assay
Classification Regulation	21 CFR 862.3250
Device Class	Class II
Device Regulation Panel	Toxicology
Product Code	DIO

Intended use

The CEDIA® Cocaine OFT Assay is intended for use in the qualitative determination of cocaine in human oral fluid at a cutoff concentration of 15 ng/mL in neat oral fluid. The specimen must be collected exclusively with the Oral-Eze™ Saliva Collection System. The assay is calibrated against benzoylecgonine and performed on the MGC240. This *in vitro* diagnostic device is intended for clinical laboratory use only.

The CEDIA Cocaine OFT Assay provides only a preliminary analytical test result. A more specific alternative method must be used to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) and Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result particularly when preliminary positive results are used.

Conditions for use

The CEDIA® Cocaine OFT Assay is for prescription professional use only in clinical chemistry laboratories. It is not for use in Point of Care settings.

Comparison of Technological Characteristics

The CEDIA® Cocaine OFT Assay is substantially equivalent to the OTI Cocaine Metabolite Intercept® MICRO-PLATE EIA. (K001197)

Comparison	Subject Device CEDIA® Cocaine OFT Assay	Predicate Device OTI Cocaine Metabolite Intercept® MICRO-PLATE EIA K001197
Intended Use	The CEDIA® Cocaine OFT Assay is intended for use in the qualitative determination of cocaine in human oral fluid at a cutoff concentration of 15 ng/mL in neat oral fluid. The specimen must be collected exclusively with the Oral-Eze™ Saliva Collection System. The assay is calibrated against benzoylecgonine and performed on the MGC240. This *in vitro* diagnostic device is intended for clinical laboratory use only. The CEDIA Cocaine OFT Assay provides only a preliminary analytical test result. A more specific alternative method must be used to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) and Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result particularly when preliminary positive results are used.	The OTI Cocaine Metabolite Intercept® MICRO-PLATE EIA is intended for use by clinical laboratories in the qualitative determination of cocaine and cocaine metabolites in oral fluid collected with the Intercept® Drugs of Abuse (DOA) Oral Specimen Collection Device. For In Vitro Diagnostic Use. The OTI Cocaine Metabolite Intercept® MICRO-PLATE EIA provides only a preliminary analytical test result. A more specific alternative chemical method should be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry/mass spectrometry (GC/MS/MS) is the preferred confirmatory method. This is a confirmation method that is currently pending SAMHSA acceptance. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when a preliminary, positive result is observed.
Principle Of the Assay	The CEDIA® Cocaine OFT Assay uses recombinant DNA technology (US Patent No. 4708929) to produce a unique homogeneous enzyme immunoassay system. The assay is based on the bacterial enzyme β-galactosidase, which has been genetically engineered into two inactive fragments i.e., enzyme acceptor (EA) and enzyme donor (ED). These fragments spontaneously reassociate to form fully active enzyme that, in the	The OTI Cocaine Metabolite Intercept® MICRO-PLATE EIA is a competitive immunoassay for the detection of cocaine and cocaine metabolites in oral fluid collected with the Intercept® Oral Specimen Collection Device. Specimen or standard is added to an EIA well in combination with an enzyme – labeled hapten derivative. In an EIA well containing an oral fluid specimen positive for cocaine or cocaine metabolites, there is a competition between cocaine and/or

SUMMARY OF CLINICAL TESTING

Qualitative Precision

All samples tested recovered accurately. Samples at levels below the cutoff read as negative and samples at levels above the cutoff read as positive.

Qualitative Cutoff Characterization

All samples tested recovered accurately, low control as negative and high control level as positive.

Interferences

Results demonstrated that there was no significant interference from endogenous and exogenous substances in oral fluid at the tested concentrations and in samples adjusted to pH range of 5 to 9.

Specificity and Cross-Reactivity

Cross-reactivity to metabolites and structurally related compounds was tested in the assay. No significant cross-reactivity was observed with other structurally unrelated compounds.

Method Comparison

The overall concordance between the CEDIA® Cocaine OFT Assay and GC/MS is 97.6%. The comparison of sample results by the CEDIA® Cocaine OFT Assay to GC/MS showed 97.6% sensitivity and 97.6% specificity.

Conclusion

As summarized, the CEDIA® Cocaine OFT Assay is substantially equivalent to the OTI Cocaine Metabolite Intercept® MICRO-PLATE EIA. Substantial equivalence has been demonstrated through performance testing to verify that the device functions as intended and that design specifications have been satisfied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Microgenics Corp.
c/o Ms. Lisa Charter
Manager, Regulatory Affairs
46360 Fremont Blvd
Fremont, CA 94538

APR 0 8 2011

Re: k101742
Trade Name: Thermo Scientific CEDIA Cocaine OFT Assay
Regulation Number: 21 CFR 862.3250
Regulation Name: Cocaine and cocaine metabolite test system.
Regulatory Class: Class II
Product Codes: DIO
Dated: April 6, 2011
Received: April 7, 2011

Dear Ms. Charter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

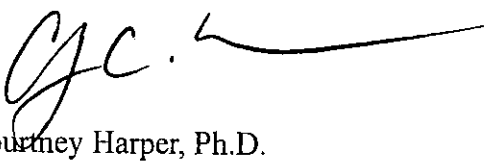
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101742

Device Name: CEDIA® Cocaine OFT Assay

Indications for Use:

The CEDIA® Cocaine OFT Assay is intended for use in the qualitative determination of cocaine in human oral fluid at a cutoff concentration of 15 ng/mL in neat oral fluid. The specimen must be collected exclusively with the Oral-Eze™ Saliva Collection System. The assay is calibrated against benzoylecgonine and performed on the MGC240. This *in vitro* diagnostic device is intended for clinical laboratory use only.

The CEDIA Cocaine OFT Assay provides only a preliminary analytical test result. A more specific alternative method must be used to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) and Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result particularly when preliminary positive results are used.

Prescription Use __X__ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101742